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PATENT COOPERATION TREATY

| From the INTERNATIONAL SEARCHING AUTHORITY | PCT | | | | | | |
|---|---|--|--|--|--|--|--|
| To: | | | | | | | |
| G.E. EHRLICH (1995) LTD. | INVITATION TO PAY ADDITIONAL FEES | | | | | | |
| 11 Menachem Begin Street | | | | | | | |
| 52521 Ramat Gan ISRAEL | (PCT Article 17(3)(a) and Rule 40.1) | | | | | | |
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| 25 APR 2007 | | | | | | | |
| 75/01/21 | | | | | | | |
| G.E. EHRLICH (1995) LT | Bate of mailing | | | | | | |
| G.E. EAKLIOT | (day/month/year) 18/04/2007 (d) | | | | | | |
| Applicant's or agent's file reference | PAYMENT DUE | | | | | | |
| 32513 | within ONE MONTH from | | | | | | |
| | the above date of mailing | | | | | | |
| International application No. | International filing date (day/month/year) | | | | | | |
| PCT/IL2006/001291 | 09/11/2006 | | | | | | |
| Applicant | , , , , , , , , , , , , , , , , , , , | | | | | | |
| SPECTRUM DYNAMICS LLC | ' | | | | | | |
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| This International Searching Authority | | | | | | | |
| 1. This international Searching Authority | | | | | | | |
| (i) considers that there are6(nur by the claims indicated XXXX/on the extra sheet: | mber of) inventions claimed in the international application covered | | | | | | |
| by the significant and | | | | | | | |
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| and it considers that the international application does not | comply with the requirements of unity of invention | | | | | | |
| (Rules 13.1, 13.2 and 13.3) for the reasons indicated belo | | | | | | | |
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| (ii) X has carried out a partial international search (see An | nex) will establish the international search report | | | | | | |
| on those parts of the international application which relate | | | | | | | |
| see annex | | | | | | | |
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| (iii) will establish the international search report on the other p to which, additional fees are paid | parts of the international application only if, and to the extent | | | | | | |
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| 2. The applicant is hereby invited, within the time limit indicated above, to pay the amount indicated below: | | | | | | | |
| EUR 1.615,00 x5 | | | | | | | |
| Fee per additional invention number of additional in | ventions total amount of additional fees | | | | | | |
| Or,xx | = | | | | | | |
| The applicant is informed that, according to Rule 40.2(c), the page 1 | ayment of any additional fee may be made under protest, | | | | | | |
| i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive. | | | | | | | |
| | | | | | | | |
| 3. Claim(s) Nos. Article 17(2)(b) because of defects under Article 17(2)(a) | have been found to be unsearchable under and therefore have not been included with any invention. | | | | | | |
| THE THE THE PARTIES OF COLOUR WHICH THE TALENCE TO LICIOUS HERE HOLDER WILL ANY INVENTION. | | | | | | | |
| Name and mailing address of the International Searching Authority | Authorized officer | | | | | | |
| European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk | Luis-Miguel Paredes Sanchez | | | | | | |
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Form PCT/ISA/206 (April 2005)

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-93, 131

A method of dynamic SPECT data acquisition and a dynamic SPECT camera characterised by the timing mechanism enabling time-binning of radioactive emissions to time periods not greater than 30 seconds and an acquisition time for a tomographic reconstruction image of 300 seconds and an intracorporeal dynamic SPECT camera.

2. claim: 94

A dynamic SPECT camera of short damping time.

3. claims: 95-103

A stationary SPECT camera.

4. claims: 104, 105, 132

A dynamic SPECT camera for time binning at dynamically varying time-bin lengths.

5. claims: 106-116, 133

A method and a dynamic SPECT camera for dynamically determining a spectral energy bin for each detecting unit.

6. claims: 117-130

A method for anatomic construction of voxels.

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The prior art has been identified as document

D1 : US 6 242 743 B1 (DEVITO RAYMOND P [US] ET AL) 5 June 2001 (2001-06-05)

and discloses

a dynamic SPECT camera (fig. 2) with an overall structure (fig. 2, ring), which defines proximal and distal ends with respect to a body; a first plurality of assemblies (fig. 2, 22), arranged on the overall structure.

forming an array of the assemblies (fig. 2, ring, col. 15, lines 33-38), each assembly comprising: a second plurality of detecting units (fig. 2, 24, col. 15, lines 33-38), each detecting unit including: a single-pixel detector, for detecting radioactive emissions (col. 15, lines 47-55); and a dedicated collimator, attached to the single-pixel detector, at the proximal end thereof, for defining a solid collection angle for the detecting unit (fig. 2, 42, col. 19, lines 5-17); and an assembly motion provider, configured for providing the assembly with individual assembly motion with respect to the overall structure (fig. 2, 25, col. 17, lines 56-60), during the acquisition of radioactive-emission data for a tomographic image; a timing mechanism, in communication with each single-pixel detector, configured for enabling time-binning of the radioactive emissions impinging upon each single-pixel detector (fig. 11); and a position-tracker, configured for providing information on the position and orientation of each detecting unit, with respect to the overall structure, substantially at all times, during the individual motion (fig. 2, 40, col. 18, lines 53-59, fig. 11), the dynamic SPECT camera being configured for acquiring a tomographic reconstruction image of a region of interest of about 15 X 15 X 15 cubic centimeters (implicitly, breast imagin, heart imaging), at a spatial resolution of at least 10 X 10 X 10 cubic millimeter (col. 19, lines 18-38).

It follows that the following technical features make a contribution over the prior art and can be considered as special technical features within the meaning of Rule 13.2 PCT:

The timing mechanism enabling time-binning of radioactive emissions to time periods not greater than 30 seconds and an acquisition time of 300 seconds.

The problem solved by these special technical features can therefore be construed as:

Finding a compromise between identifying real coincident events and achieving a high detection signal.

The special technical feature of group I, as defined in Rule 13.2 PCT, therefore is:

The timing mechanism enabling time-binning of radioactive emissions to time periods not greater than 30 seconds and an acquisition time of 300 seconds.

Group II (claim 94) yields the non-disclosed (by the prior art document D1) potential special technical feature of:

A braking mechanism.

The problem to be solved by this claim could thus be said to reduce mechanical vibrations which might interfere with the data acquisition.

The special technical feature of group II not known from the above mentioned prior art, is:

A braking mechanism.

Group III (claims 95-103) yields the non-disclosed (by the prior art document D1) potential special technical features of:

A stationary SPECT camera with an assembly motion provider providing the assembly with motion prior to the acquisition of data, acquiring tomographic reconstruction of a region of interest while stationary for the whole duration of the tomographic image acquisition.

The problem to be solved by these claims could thus be said to determine a region of interest during a pre-scan.

The special technical feature of group III, not known from the above mentioned prior art, is:

A stationary SPECT camera with an assembly motion provider providing the assembly with motion prior to the acquisition of data, acquiring tomographic reconstruction of a region of interest while stationary for the whole duration of the tomographic image acquisition.

Group IV (claims 104, 105, 132) yields the non-disclosed (by the prior art document D1) potential special technical features of:

A timing mechanism for time binning to time bins of dynamically varying time-bin lenghts.

The problem to be solved by these claims could thus be said to compensate for the uptake curve of a radiopharmaceutical as well as for different parts of cardiac cycles.

The special technical feature of group IV, not known from the above mentioned prior art, is:

A timing mechanism for time binning to time bins of dynamically varying time-bin lenghts.

Group V (claims 106-116, 133) yields the non-disclosed (by the prior art document D1) potential special technical features of:

A selection mechanism for enabling a selection of a spectral energy bin to be used for each detecting unit and a lookup system of recommended spectral energy bin values which is configured for dynamically determining the spectral energy bin for each detecting unit.

The problem to be solved by these claims could thus be said to eliminate contributions from other radiopharmaceuticals.

The special technical feature of group V, not known from the above mentioned prior art, is:

A selection mechanism for enabling a selection of a spectral energy bin to be used for each detecting unit and a lookup system of recommended spectral energy bin values which is configured for dynamically determining the spectral energy bin for each detecting unit. Group VI (117-130) yields the non-disclosed (by the prior art document D1) potential special technical features of:

A method for anatomic construction of voxels with constructing an anatomic system of voxels in which the voxel boundaries are aligned with boundaries of structural objects of the region of interest, performing radioactive-emission imaging and reconstruction utilizing the anatomic system of voxels.

The problem to be solved by these claims could thus be said to avoid a smearing effect if different tissue types appear in a same voxel.

The special technical feature of group VI, not known from the above mentioned prior art, is:

A method for anatomic construction of voxels with constructing an anatomic system of voxels in which the voxel boundaries are aligned with boundaries of structural objects of the region of interest, performing radioactive-emission imaging and reconstruction utilizing the anatomic system of voxels.

From the above, it would seem that there are no technical features in the claimed inventions, which can be seen as common or corresponding special technical features within the meaning of Rule 13.2 PCT.

In determining a possible relationship between these 6 subjects, such as a common inventive concept, it has been found that the timing mechanism enabling time-binning of radioactive emissions to time periods not greater than 30 seconds and an acquisition time of 300 seconds does not contribute to the aims of:

- a) reducing mechanical vibrations which might interfere with the data acquisition.
 - b) determining a region of interest during a pre-scan,
- c) compensating for the uptake curve of a radiopharmaceutical as well as for different parts of cardiac cycles,
 - d) eliminating contributions from other radiopharmaceuticals,
- e) avoiding a smearing effect if different tissue types appear in a same voxel.

Furthermore, neither

- a) a braking mechanism, nor
- b) a stationary SPECT camera with an assembly motion provider providing the assembly with motion prior to the acquisition of data, acquiring tomographic reconstruction of a region of interest while stationary for the whole duration of the tomographic image acquisition,

c) a timing mechanism for time binning to time bins of dynamically

varying time-bin lenghts, nor

- d) a selection mechanism for enabling a selection of a spectral energy bin to be used for each detecting unit and a lookup system of recommended spectral energy bin values which is configured for dynamically determining the spectral energy bin for each detecting unit, nor
 - e) a method for anatomic construction of voxels with constructing

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an anatomic system of voxels in which the voxel boundaries are aligned with boundaries of structural objects of the region of interest, performing radioactive-emission imaging and reconstruction utilizing the anatomic system of voxels,

does contribute to the aim of finding a compromise between identifying real coincident events and achieving a high detection signal.

The only common concept to be found for some of the groups (groups I, II, IV, V) is a dynamic SPECT camera but this is known from document D1.

Furthermore, there are no further features available by means of which a relationship between the subjects of the 6 different sets of claims may be established.

Consequently, neither the objective problem underlying the subjects of the 6 claimed inventions, nor their solutions defined by the special technical features allow for a relationship to be established between the said inventions.

In conclusion, therefore, the 6 groups of claims are not linked by common or corresponding special technical features and define 6 different inventions not linked by a single general inventive concept. Hence, the application does not meet the requirements of Unity of Invention as defined in Rule 13.1 PCT.

Annex to Form PCT/ISA/206 COMMUNICATION RELATING TO THE RESULTS OF THE PARTIAL INTERNATIONAL SEARCH

International Application No PCT/IL2006/001291

- 1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
- see 'Invitation to pay additional fees' 2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
- 3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
- 4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

| C. DOCUME | ENTS CONSIDERED TO BE RELEVANT | |
|------------|---|-----------------------|
| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| A | US 6 242 743 B1 (DEVITO RAYMOND P [US] ET AL) 5 June 2001 (2001-06-05) cited in the application figures column 15, line 33 - line 38 column 15, line 47 - line 55 column 17, line 56 - line 60 column 18, line 45 - line 59 column 19, line 5 - line 17 column 19, line 18 - line 38 column 24, line 9 - line 30 column 25, line 14 - line 39 claims 1,5,6,67 | 1,73,131 |
| A | GB 2 031 142 A (SHAW R) 16 April 1980 (1980-04-16) page 4, line 48 - line 57; figures -/ | 1,73,131 |

- Further documents are listed in the continuation of box C.
- X Patent family members are listed in annex.

- Special categories of cited documents:
- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Annex to Form PCT/ISA/206 COMMUNICATION RELATING TO THE RESULTS OF THE PARTIAL INTERNATIONAL SEARCH

International Application No
PCT/IL2006/001291

| Category Cliation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|-----------------------|
| | |
| AOI T ET AL: "Absolute quantitation of regional myocardial blood flow of rats using dynamic pinhole SPECT" 2002 IEEE NUCLEAR SCIENCE SYMPOSIUM CONFERENCE RECORD. / 2002 IEEE NUCLEAR SCIENCE SYMPOSIUM AND MEDICAL IMAGING CONFERENCE. NORFOLK, VA, NOV. 10 - 16, 2002, IEEE NUCLEAR SCIENCE SYMPOSIUM CONFERENCE RECORD, NEW YORK, NY: IEEE, US, vol. VOL. 3 OF 3, 10 November 2002 (2002-11-10), pages 1780-1783, XP010663867 ISBN: 0-7803-7636-6 abstract; figures | 1,73,131 |
| US 2004/204646 A1 (NAGLER MICHAEL [IL] ET AL) 14 October 2004 (2004-10-14) figures page 5, paragraph 96 page 6, paragraph 101 - page 7, paragraph 110 page 7, paragraph 121 - paragraph 123 page 8, paragraph 137 | 73 |
| US 5 846 513 A1 (CARROLL ROBERT G [US] ET AL CARROLL ROBERT G [US] ET AL) 8 December 1998 (1998–12–08) column 4, line 61 - column 6, line 60; figures | 73 |

Patent Family Annex

information on patent family members

International Application No
PCT/IL2006/001291

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|--|----|---------------------|-------------------------|------------------|
| US 6242743 | B1 | 05-06-2001 | NONE | |
| GB 2031142 | Α | 16-04-1980 | NONE | |
| US 2004204646 | A1 | 14-10-2004 | NONE | |
| US 5846513 | A1 | | NONE | |